DEC 2 1 2001

Appendix 25 - *revised*
510(k) Summary of Safety and Effectiveness

Vertis Neuroscience, Inc.
Percutaneous Neuromodulation Therapy (PNT) ™ Control Unit and Accessories

K011702

General Information

Classification	Class II
Trade Name	Percutaneous Neuromodulation Therapy (PNT) Nerve Stimulation System
Submitter	Vertis Neuroscience, Inc. 2101 Fourth Avenue, Suite 200 Seattle, Washington, USA 98121
Contact	Lori Glastetter Vice President, Regulatory Affairs/ Quality Assurance

Substantially Equivalent Devices

Manufacturer	Substantially Equivalent devices	510(k)
Empi, Inc. St. Paul, MN	EPIX Tens Device System Model EPIX VT Model EPIX XL	K970203 K951903
Rehabilicare, Inc. New Brighton, MN	SMP-Plus™ Model 4930	K982410
Chattanooga Group, Inc. Hixson, TN	Intelect ® Legend Stim Model IFC2 (catalog #INT002)	K924666
Medtronic, Inc Minneapolis, MN	Mattrix ® Neurostimulation System Receiver model: 3272 Transmitter model: 3210	K982902
TECA Corporation Pleasantville, NY	TECA Disposable Monopolar Needles 902-DMFxx-TP series 892-DMGxx-TP series	K973442
Medtronic, Inc. Minneapolis, MN	DMN™ Disposable Monopolar Needle Electrodes DMFxx series DMNxx series	K950314
Medtronic, Inc. Minneapolis, MN	Resume II Lead Model 3587a	K915540

Intended use

Percutaneous Neuromodulation Therapy (PNT) is indicated for the symptomatic relief and management of chronic or intractable low back pain and/or as an adjunctive treatment in the management of post-surgical low back pain and post-trauma low back pain.

The PNT Control Unit is to be used with a PNT Safeguide Kit – Lumbar.

Device Description

The Vertis PNT System is designed for delivering percutaneous electrical stimulation (termed: Percutaneous Neuromodulation Therapy - PNT). The Vertis PNT System is intended to be used in pain management by a physician (e.g., anesthesiologists or physical medicine and rehabilitation physicians) or on the order of a physician (e.g., by a physical therapist) in a clinic environment. It is not intended for patient use. The device system includes 3 major components:

- the *Vertis PNT Control Unit* - a software-driven, five channel, AC powered nerve stimulator which generates the electrical stimulus;
- the sterile *Safeguides* – which are sterile, needle electrodes, and
- the *Patient Cable* - which interconnects the PNT Control Unit to the electrodes

Bench/Animal Testing

Extensive bench and animal was conducted on the Vertis PNT System and included performance and safety testing. The Vertis PNT System conforms to applicable sections of the technical references and FDA-recognized consensus standards noted below. Additionally, the PNT Control Unit software was validated per recognized validation techniques.

Results: All testing of the products yielded acceptable results prior to commercial distribution.

ANSI/AAMI NS4-1985 Transcutaneous Electrical Nerve Stimulators, approved 5-20-86.
ANSI/AAMI ES1 1993 - Safe Current Limits for Electromedical Apparatus, approved 12-2-93
ANSI/AMI NS15-1995 Implantable Peripheral Nerve Stimulators, approved 2-1-95
IEC60601-1:1993 Medical Electrical Equipment, Part 1: General Requirements for Safety and Amendments A1:1991, A2:1995.
IEC 60601-1-2 First Edition 1993-4 Medical Electrical Equipment, - Part 1: General Requirements for Safety: Electromagnetic Compatibility – Requirements and Tests (tested in accordance to the IEC 61000 series).
IEC 60601-1-4:1996 Medical Electrical Equipment, Part 1: General Requirements for Safety, Part 2: Collateral Standard: Programmable electrical medical systems.
IEC 60601-2-10:1987 Medical Electrical Equipment, Part 2: Particular Requirements for the Safety of Nerve and Muscle Stimulators.
EN (CEN) 1441:1997 Medical Devices – Risk Analysis.

ANSI/AAMI/ISO 15223: 2000 Medical Devices – Symbols to be used with Medical Device Labels, Labeling and Information to be Supplied, approved 3-13-00.
IEC 60601-2-10:1987 Medical Electrical Equipment, Part 2: Particular Requirements for the Safety of Nerve and Muscle Stimulators.
ANSI/AAMI/ISO 11137: 1994 Sterilization of Health Care Products – Requirements for Validation and Routine Control –Radiation Sterilization; using Method 1 as described per AAMI/ISO TIR No. 13409: 1996 Sterilization of Health care Products – Radiation Sterilization – Substantiation of 25kGy as a Sterilization Dose for Small or Infrequent Production Batches.
ANSI/AAMI/ISO 10993-1:1997, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing.

Clinical Testing

Under the auspices of an Investigational Device Exemption, Vertis conducted a prospective clinical study evaluating the safety and effectiveness of percutaneous neuromodulation therapy.

The Vertis clinical trial was reviewed and approved in November 2000. The trial commenced shortly thereafter at multiple United States clinical sites. The trial was completed in March 2001. During the multi-week investigational protocol, there were a total of 2150 electrode placements in 215 PNT therapy sessions with patients.

Results: The clinical trial demonstrated the safety and effectiveness of the percutaneous neuromodulation therapy.

Summary of Substantial Equivalence

Therefore, due to the similarity of design features, materials, test results, clinical results and indicated use to other predicate devices, Vertis believes the Vertis PNT System does not raise any new safety or effectiveness issues and is substantially equivalent to currently available nerve stimulators, electrodes and accessories that have been determined to be substantially equivalent to devices in commercial distribution prior to May 28, 1976.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2001

Lori J. Glastetter
Vice President, Regulatory Affairs/Quality Assurance
Vertis Neuroscience, Inc.
2101 Fourth Avenue, Suite 200
Seattle, Washington 98121

Re: K011702/S1
Trade/Device Name: Vertis Percutaneous Neuromodulation Therapy (PNT) Stimulation System (Vertis PNT Control Unit and Vertis PNT Lumbar Safeguard Kit)
Regulation Number: 21 CFR 882.5890 and 21 CFR 882.1350
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief and Needle Electrode
Regulatory Class: Class II
Product Code: NHI and GXZ
Dated: September 24, 2001
Received: September 25, 2001

Dear Ms. Glastetter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011702

Device Name: Vertis PNT System

Indications For Use:

Percutaneous Neuromodulation Therapy (PNT) is indicated for the symptomatic relief and management of chronic or intractable low back pain and/or as an adjunctive treatment in the management of post-surgical low back pain and post-trauma low back pain.

The PNT Control Unit is to be used with a PNT Safeguide Kit – Lumbar.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

(Optional Format 3-10-98)

510(k) Number K011702